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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,239	03/23/2004	Rosario Lizio	104085-393-CON	5035

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,239	LIZIO ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-26* is/are pending in the application.

4a) Of the above claim(s) *1-8,13 and 15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/944,060.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendment of 12/17/07 are acknowledged. As a result of Applicant's amendment to new product limitations not claimed by original presentation, a new search was undertaken, art found and applied (now under 103 in combination with the previous art of record), and the action therefore made FINAL. Applicant has added new claims 25-26. Claims 9-12 and new claims 25-26 are under examination on the merits.

Election/Restrictions

As noted previously, Applicant's election without traverse of Group II, claims 9-12 (product by process) in the reply filed on 3/21/07 is acknowledged. Claims 1-8 and 13-24 are withdrawn from consideration. At the outset it is noted that the elected invention is to a *product* (claimed via product-by-process language).

Claim Rejections - 35 USC § 102

The rejection of claims 9-12 under 35 U.S.C. 102(b) as being anticipated by Eljamal et al. (US 5,993,783) no longer applies under 102 based on Applicant's product size limitations claim amendment which are not expressly taught in Eljamal et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-12 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (US 5,955,439) alone or Eljamal et al. (US 5,993,783) in view of Green et al. (US 5,995,439).

Green et al. teach an insulin particle size of the particulate (e.g. micronised) medicament should be such as to permit substantially all of the particles to be potentially available for inhalation into the lungs upon administration of the powder composition having "*at least 90%,* preferably at least 95% by weight of the particles will have a diameter of less than 15 micrometers, preferably in the range of 1 to 10 micrometers, *for example 1 to 5 micrometers*" (col. 1, lines 44-61). Green does not expressly word it as Applicant has in the sense of "< 4.9 micrometers".

Eljamal et al. was discussed previously under 102, and teach a solid, fine-particulate pharmaceutical preparation for inhalatory administration comprising insulin in e.g. a dry powder inhaler or blister inhaler (entire document, see e.g. col. 3, 7, and 8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to arrive at a solid fine-particulate powder preparation (composition) for lung inhalation wherein 90% (or more) of the particulate has a particle diameter of < 4.9 micrometers in Green et al. alone or Eljamal et al. in view of Green et al., because both references advantageously teach the administration of fine-particulate compositions of insulin for lung administration, and Green et al. arguably teaches the exact range (other than being .1% different) of 90% of the particulate being under 5 micrometers in size, and the selection of any size therein would have merely been a matter of routine processing, depending on the ultimate

size between 1 and 5 micrometers, desired therein, based on the predictable results of any size therein as capable of known passage via lung alveoli tissue into the vascular system for systemic effect.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

As mentioned previously, and recited again for continuity of record:

The guiding sections of the MPEP, regarding the above, are provided for Applicant's convenience:

2113 [R-1] Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. ***If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."*** In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was

directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

>The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)

2173.05(p) [R-5] Claim Directed to Product-By- Process or Product and Process

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention.

I. PRODUCT-BY-PROCESS

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. In re Luck, 476 F.2d 650, 177

USPQ 523 (CCPA 1973); In re Pilkington, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); In re Steppan, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, **so long as it is clear that the claim is directed to the product and not the process.**

An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms. Ex parte Pantzer, 176 USPQ 141 (Bd. App. 1972).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 3/15/2008

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654